

10/070146

JP05 Rec'd P37770 01 MAR 2002

Practitioner's Docket No. 2245/108

CHAPTER II

Preliminary Classification:

Proposed Class:

Subclass:

TRANSMITTAL LETTER
TO THE UNITED STATES ELECTED OFFICE (EO/US)

(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

PCT/GB00/03377	04 September 2000 (4.09.00)	04 September 1999 (4.09.99)
International Application Number	International Filing Date	International Earliest Priority Date

TITLE OF INVENTION: DELIVERY DEVICE

APPLICANT(S): Braithwaite, Philip

Box PCT
Commissioner for Patents
Washington D.C. 20231
ATTENTION: EO/US


CERTIFICATION UNDER 37 C.F.R. SECTION 1.10*

(Express Mail label number is **mandatory**.)(Express Mail certification is **optional**.)

I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date 01 March 2002, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL 603053817 US, addressed to the: Commissioner for Patents, Washington, D.C. 20231, Attn: EO/US.

Robert M. Asher

(type or print name of person mailing paper)



Signature of person mailing paper

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. Section 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

***WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. Section 1.10(b).
"Since the filing of correspondence under [Section] 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Transmittal Letter to the United States Elected Office (EO/US)--page 1 of 4)

1. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. Section 371:

- a. This express request to immediately begin national examination procedures (35 U.S.C. Section 371(f)).
- b. The U.S. National Fee (35 U.S.C. Section 371(c)(1)) and other fees (37 C.F.R. Section 1.492) as indicated below:

2. Fees

CLAIMS FEE*	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS	42 - 20 =	22	x \$18.00 =	\$396.00
	INDEPENDENT CLAIMS	6 - 3 =	3	x \$84.00 =	\$252.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$280.00				\$280.00
BASIC FEE	U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in Section 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in Section 1.445(a)(2) to the U S PTO: where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 C.F.R. Section 1.492(a)(5)) \$890.00				\$890.00
	Total of above Calculations				= \$1,818.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed. (note 37 CFR Sections 1.9, 1.27, 1.28)				- \$0.00
	Subtotal				\$1,818.00
	Total National Fee				\$1,818.00
	Fee for recording the enclosed assignment document \$40.00 (37 C.F.R. Section 1.21(h)). See attached "ASSIGNMENT COVER SHEET".				\$0.00
TOTAL	Total Fees enclosed				\$1,818.00

A check in the amount of \$1,818.00 to cover the above fees is enclosed.

3. A copy of the International application as filed (35 U.S.C. Section 371(c)(2)) has been transmitted by the International Bureau.

Date of mailing of the application (from form PCT/IB/308):

4. A translation of the International application into the English language (35 U.S.C. Section 371(c)(2)) is not required as the application was filed in English.

5. Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. Section 371(c)(3)) have not been transmitted. Applicant chose not to make amendments under PCT Article 19.

Date of mailing of Search Report (from form PCT/ISA/210): 05 January 2001

6. A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. Section 371(c)(3)) has not been transmitted for reasons indicated in section 5.

7. A copy of the international examination report (PCT/IPEA/409) is transmitted herewith.

8. Annex(es) to the international preliminary examination report is/are transmitted herewith.

9. A translation of the annexes to the international preliminary examination report is not required as the annexes are in the English language.

10. An oath or declaration of the inventor (35 U.S.C. Section 371(c)(4)) complying with 35 U.S.C. Section 115 will follow.

II. Other document(s) or information included:

11. An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a) is transmitted herewith.

12. An Information Disclosure Statement under 37 C.F.R. Sections 1.97 and 1.98 will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. Section 371(c).

13. Additional documents:

- a. International Publication No. WO01/17595
Specification, claims and drawing

14. The above items are being transmitted before 30 months from any claimed priority date.

AUTHORIZATION TO CHARGE ADDITIONAL FEES

The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No.: 19-4972

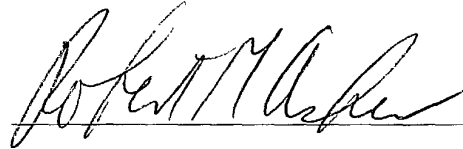
37 C.F.R. Section 1.492(a)(1), (2), (3), and (4) (filing fees)

37 C.F.R. Section 1.492(b), (c), and (d) (presentation of extra claims)

37 C.F.R. Section 1.17 (application processing fees)

37 C.F.R. Section 1.17(a)(1)-(5) (extension fees pursuant to Section 1.136(a))

Date: 01 March 2002



Robert M. Asher
Registration No. 30,445
Bromberg & Sunstein LLP
125 Summer Street
Boston, MA 02110-1618
US
617-443-9292
Customer No. 2101

Rec'd PCT/PTC 01 MAR 2002

DELIVERY DEVICE

This invention relates to a novel form of material delivery device, for example, a medicament delivery device, such as an inhaler. In particular the invention provides
5 a novel form of dry powder inhaler and a method of delivering a medicament.

Dry powder inhalers are known, such as TECHNOHALER, being developed by Innovata Biomed in the UK. Such a device is described in International Patent Application No WO 93/16748 (PCT/GB93/00335). WO '748 describes an inhaler
10 which comprises a disc like magazine having a plurality of medicament carrying receptacles around its periphery. Each receptacle comprises a spool housed in a spool carrier. Each spool has a flange at each end which form a tight slidable fit within the body of the spool carrier. The space left between the body of the spool and the spool carrier is filled with an appropriate medicament.

15

The known TECHNOHALER is provided with suitable indexing means, including a push button and a ratchet mechanism which engages with the upper surface of the disc. Depression of the push button urges a push rod to push the spool, which is adjacent the inhalation passage of the inhaler, downwards and almost fully out of the
20 spool carrier, and into the inhalation passage. As the spool is pushed into the inhalation passage, it carries with it the measured quantity of medicament which it has been used to contain inside the magazine. The user can then inhale through the mouthpiece so as to take up the drug now released into the inhalation passage. The upper flange of the spool remains, however, held by the lower part of the receptacle.

25 When the user then releases push button, the ratchet mechanism causes the disc to rotate by one step so that the next receptacle is brought into register with the inhalation passage. The inhaler is thus reset and ready for delivery of another dose of drug. The "empty" spool not having been pushed fully out of the first receptacle, continues to move round with the first receptacle, supported by the lower guide.

30

In the inhaler of the prior art whilst the spool magazine lies essentially in the same plane as the as the mouthpiece of the inhaler, the push rod acts on a spool in a perpendicular plane.

5 We have now found a novel form of medicament delivery device in which a push rod lies in essentially the same plane as the delivery orifice of the device and actuates the spool in a direction which is coaxial with the delivery orifice of the device. Thus when a plurality of spools are arranged radially in a magazine, such that the longitudinal axis of the spools lie in the same plane as the magazine and the spool
10 may be expressed radially from the magazine. This has the advantage that, *inter alia*, a significantly slimmer device may be produced. Furthermore, the radial expression of the spools means that more than one magazine can be placed in the device and thus, *inter alia*, the device may deliver higher dosages, combination therapies and/or provide medication over a longer period of time.

15 Thus, according to the invention we provide a delivery device comprising a rotatable metering member adapted to dispense a measured amount of material, a material delivery passage and a material delivery orifice, and at least one actuator member adapted to move the metering member from a material retaining position to a
20 material dispensing position characterised in that the actuator member moves in a substantially radial direction and actuates the metering member in a substantially radial direction.

The device of the invention has utility in a variety of areas, including, for example,
25 medicament delivery. Thus, it is especially suited as an inhaler and especially a dry power inhaler (DPI).

According to a preferred feature of the invention the device is provided with a plurality of metering members housed in a magazine, preferably a substantially
30 circular magazine. In an especially preferred embodiment a plurality of magazines may be loaded into the delivery device of the invention, e.g. a pair of magazines.

When the metering member is in the medicament retaining position it is preferably out of communication with the inhalation passage and whilst the metering member is in the medicament dispensing position it is preferably in communication with the inhalation passage.

5

The metering member is of such dimensions as to be able to pass into the inhalation passage. The metering member may comprise those described in WO 93/16748. Thus, in one embodiment the metering member may comprise a spool housed in a spool carrier. The spool carrier acts as a conduit for the spool to communicate with the inhalation passage. Thus the spool will be provided with a flange at each end such that the flanges are in sealing engagement with the inner walls of the conduit and a space exists between the inner walls of the conduit and the non-flanged portion of the spool. In the filled metering member, the space is taken up by a measured dosage of medicament. Indeed, the plug, flanges and conduit are so dimensioned so as to predetermine the amount of medicament available. In an alternative embodiment of the invention the metering member may comprise a medicament container with a closed end and an open end, a cap adapted to abut the open end of the container and a sleeve adapted to overlap the open end of the container and the cap. Reference hereinafter to a spool and spool carrier is intended to encompass a capped cartridge as hereinbefore described.

20

The spool and spool carrier is generally that described in the prior art patent application. However, instead of the spool being mounted in a vertical position each spool is essentially horizontally mounted. For the sake of clarity, the spools are positioned in the same plane as the plane of the disc magazine. The push rod used to eject the spool from the spool carrier therefore operates radially from the centre of the disc and does not push the spool out of the disc plane.

25

The actuator member may comprise a push rod mechanism which may be substantially similar to that known conventionally save that it acts radially.

30

Alternatively, when a plurality of magazines is used the actuator member may, for example, comprise a pair of push rods.

As hereinbefore described a significant advantage of the device of the invention is
5 that it can be used to deliver combination therapies if desirable.

Increasingly, patients are required to take more than one medicine and this is no less the case in the treatment of bronchial disorders. Thus, for example, combination therapies such as a steroid with a β_2 agonist, eg fluticasone and salmeterol, have been
10 commercially successful. To date, the administration of such combination therapies comprises the use of a predetermined formulation either as a dry powder, eg in a gelatine capsule or a foil blister; or alternatively as a metered dose aerosol. However, this approach suffers from the disadvantage, inter alia, that the medical practitioner is restricted in that it is not possible to vary the quantities of the two
15 medicaments administered. Thus, there has therefore been a long felt need for a dry powder inhalation system which permits the administration of combination therapies.

It is within the scope of this invention for more than two medicaments to be administered, however, it is considered most likely that dual combination therapies
20 would be preferred by the medical profession. Thus the description hereinafter will generally refer to an inhaler adapted to administer a dual combination medicament, but it would be well understood by one skilled in the art that these references could be construed to multiple combinations.

25 Thus according to a further feature of the invention we provide a dry powder inhaler as hereinbefore described characterised in that the inhaler is adapted to take a plurality of disc magazines. The medicament encapsulated in the spool carriers of the two disc magazines may be the same or different. In one embodiment the medicaments are different and thus the inhaler is used to deliver a combination
30 therapy. Alternatively, the medicament encapsulated by the spool carrier may itself be a combination therapy.

In a further embodiment of the invention a medicament delivery device, eg an inhaler, comprises a pair of disc magazines. Such a device may preferentially be provided with means for engaging a first magazine whilst disengaging a second magazine and which is moveable from an engaging to a disengaging position and vice-versa.

Such means may comprise male and female interlocking members. Preferentially, the disc magazine is provided with a female member and a drive means is provided with a male member.

In an especially preferred embodiment a drive plate is provided with a male member and is adapted to engage with the drive means.

The male member may comprise a resilient protrusion which is resiliently biased towards a second disc magazine, but is constructed so as to be urged to engage with a female member of a first disc magazine, such that when the urging means is removed the male member is biased towards and engages with the second magazine.

A variety of medicaments may be administered by using the inhaler of the invention, such medicaments may have a systemic or non-systemic activity on the patient. Such medicaments are generally (but not limiting) antibiotics, bronchodilators or other anti-asthma drugs. Such medicaments include, but are not limited to β_2 -agonists, e.g. fenoterol, formoterol, pirbuterol, reproterol, rimiterol, salbutamol, salmeterol and terbutaline; non-selective beta-stimulants such as isoprenaline; xanthine bronchodilators, e.g. theophylline, aminophylline and choline theophyllinate; anticholinergics, e.g. ipratropium bromide; mast cell stabilisers, e.g. sodium cromoglycate and ketotifen; bronchial anti-inflammatory agents, e.g. nedocromil sodium; and steroids, e.g. beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations thereof.

Specific combinations of medicaments which may be mentioned include combinations of steroids, such as, beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations of two β_2 -agonists, such as, formoterol and salmeterol. It is also within the scope of this invention to include combinations of one or more of the aforementioned steroids with one or more of the

Further medicaments which may be mentioned include systemically active materials, such as, proteinaceous compounds and/or macromolecules, for example, hormones and mediators, such as insulin, human growth hormone, leuprolide and alpha interferon; growth factors, anticoagulants, immunomodulators, cytokines and nucleic acids.

When dual disc magazines are used the inhaler will be provided with two radially acting push rod mechanisms. These mechanisms may be adapted to operate together, independently or sequentially.

The invention will now be illustrated by way of example only and with reference to the accompanying drawings, in which:

20

Figure 1 is a cross-sectional view of a spool and spool carrier;

Figure 2 is a perspective view of a single disc magazine comprising spools;

Figure 3 is a schematic representation of the ejection of a spool from the spool carrier;

25

Figure 4 is a perspective view of a combination therapy disc magazine; and

Figure 5 is a cross-sectional view of the combination therapy mechanism.

Figure 6 is a perspective view of a disc magazine provided with an empty spool holder;

Figure 7 is a perspective view of a pair of disc magazines provided with a drive plate;

30

Figure 8 is a schematic representation of a pair of magazines provided with a drive plate;

Figure 9 is a schematic representation of the carousel in operation with dual plunger rods;

5 Figure 10 is a schematic representation of the device when the first (lower) carousel has completed a 360° rotation;

Figure 11 is a perspective view of an alternative embodiment of a drive disc;

Figure 12 is a perspective view of a pair of disc magazines with a drive disc;

10 Figure 13 is a schematic representation of a device in operation with a dual plunger rod; and

Figure 14 is a schematic representation of a device when the first (lower) carousel has completed a 360° rotation.

15 With reference to Figure 1. A single medicament dose unit (1) is comprised of a spool (2), a spool carrier (3) and a single dose of medicament (4), for use in a dry powder inhaler. The spool (2) comprises a longitudinal body (5) and terminal flanges (6 and 7) at each end. The sides (8 and 9) of the flanges (6 and 7) form a seal and a tight slidable fit with the inner walls (10 and 11) of the spool carrier (3). The length of the spool (2) and the length of the spool carrier (3) are substantially the same.

20 Each flange is provided with an external face (12 and 13).

With reference to Figures 2 and 3. A plurality of spools (2) and carriers (3) are joined in a disc to form a magazine. The plurality of dose units (1) arranged radially around the circumference of the magazine (14). The inhalation device is provided

25 with a dispensing mechanism (not shown) and a push rod (15) which also acts radially. The push rod (15) when actuated operates in the radial plane of the magazine (14) ejecting a spool (2) radially from the spool carrier (3) into the inhalation passage (not shown). The spool (2) remains in the plane of the magazine (14) and the flange (7) remains in co-operation with the spool carrier (3) so that it can

30 move out of the inhalation passage upon rotation of the magazine (14).

With reference to Figures 4 and 5. A "double decker" arrangement is achieved by joining a first magazine (14) with a second magazine (16). The inhaler mechanism is provided with a first push rod (5) and a second push rod (17). The push rods may be actuated jointly, separately or sequentially optionally allowing medicament to be dispensed at the same time in the spool from the first magazine (14) as in the spool from the second magazine (16).

With reference to Figure 6, a spool carrier magazine (101) comprises a disc provided with a plurality of radially mounted spool carriers (102). Each of the spool carriers (102) (save for one) is provided with a spool (103). One of the spool carriers (104) is empty and is provided with a cut away portion (105).

With reference to Figure 7, a pair of spool carrier magazines (101a and 101b) are provided. A drive disc (106) comprises a substantially planar annular disc. The inner surface (107) of the drive disc (106) is provided with a plurality of teeth (108) which are adapted to engage with a drive means (not shown).

Adjacent to the periphery (109) of the drive disc (106), the disc is provided with an aperture (110) through which protrudes an out of plane resilient male member (111). The male member (111) is biased towards one of the magazines. By way of example only, the embodiment described is one in which the male member (111) is biased towards the uppermost magazine (101b), although it should be understood that the present application should be read to also encompass an embodiment in which the male member may be biased towards the other magazine (101a).

The drive disc (106) is positioned adjacent to the first magazine (101a) such that the male member (111) overlies the cut away portion (105) and the empty spool carrier (104). When the second magazine (101b) is positioned in place it is arranged such that a filled spool carrier (102) overlies the male member (111). The circumferential surface (112) rests against the male member (111) and urges it into an engaging position with the empty spool carrier (104).

Thus, in use, when the annular drive disc (106) is rotated, the male member (111) engages with the empty spool carrier (104) to rotate the first magazine (101a) whilst the second magazine (101b) is disengaged and therefore remains unmoved.

5

With reference to Figures 8-10, the assembly of the system is illustrated. Thus, the assembly (113) comprises a chassis (114) and the drive disc (106) is placed above the magazine (101a). The male member (111) is biased away from the magazine (101a) and therefore protrudes above the plane of the drive disc (106). The second upper magazine (101b) is then positioned above the drive disc (106).

10

The male member (111) comprises a substantially triangular shaped tab with a first surface (116), a second surface (117), a hinged end (118) and a distal end (119). Optionally, the hinged end (118) may be provided with a groove (119) to facilitate the flexible movement of the male member (111). In its free position the male member (111) rests such that the first surface (116) lies in the plane of the drive disc (106) and the second surface (117) lies out of the plane and protrudes from the drive disc (111).

15

When the second, upper magazine (101b) is in place, the lower, outer surface (120) of the spool carrier magazine is urged against the second surface (117) of the male member (111). This urges the second surface (117) to lie in the plane of the drive disc (106) and therefore the first surface (116) lies out of the plane, enabling it to engage with the empty spool carrier (104).

20

A push rod (121) is also provided which comprises a pair of spool prodders (122a and 122b). The push rod (121) is connected to an actuator means (not shown). A chassis lid (114a) is provided to close the system.

25

With reference to Figures 11 to 14, a further embodiment is illustrated in which the male member (111a) protrudes beyond the peripheral edge (123) of the drive disc

(106). The chassis (114a) is provided with two sets of guide rails (124 and 125). The device is assembled so that the male member (111a) is tensioned and the peripheral end (126) of the male member (111) held in the guide rail (124). When the lower magazine has rotated through approximately 360°, the male member (111a) reaches a break in the guide rails (124 and 125), thus allowing the male member (111a) to be urged towards the second magazine and into the second guide rail (125).

10

15

20

25

30

CLAIMS

1. A delivery device comprising a rotatable metering member adapted to dispense a measured amount of material, a material delivery passage and a material delivery orifice, and at least one actuator member adapted to move the metering member from a material retaining position to a material dispensing position characterised in that the actuator member moves in a substantially radial direction and actuates the metering member in a substantially radial direction.
2. A delivery device according to claim 1 characterised in that the device comprises a plurality of metering members adapted to dispense a measured amount of material, said metering members being held in a rotatable magazine.
3. A delivery device according to claim 2 characterised in that the device is adapted to take a plurality of magazines.
4. A delivery device comprising a plurality of rotatable magazines, each magazine being provided with a plurality of metering members adapted to dispense a measured amount of material, a material delivery passage and a material delivery orifice, and at least one push rod adapted to move a metering member from a material retaining position to a material dispensing position.
5. A delivery device according to claims 1 or 4 characterised in that the material is a medicament.
6. A delivery device according to claims 1 or 4 characterised in that the material is a dry powder.
7. A delivery device according to claims 2 or 4 characterised in that the magazine is substantially circular.

8. A delivery device according to claims 3 or 4 characterised in that the device comprises a pair of magazines.
- 5 9. A delivery device according to claim 8 characterised in that the device is provided with means for engaging a first magazine whilst disengaging a second magazine and which engaging means is moveable from an engaging to a disengaging position and vice-versa.
- 10 10. A delivery device according to claim 9 characterised in that the engaging means comprises male and female interlocking members.
11. A delivery device according to claim 10 characterised in that the magazine is provided with a female member and a drive means is provided with a male member.
- 15 12. A delivery device according to claim 11 characterised in that a drive plate is provided with a male member and is adapted to engage with the drive means.
- 20 13. A delivery device according to claim 12 characterised in that the male member comprises a resilient protrusion which is resiliently biased towards a second magazine, but is constructed so as to be urged to engage with a female member of a first disc magazine, such that when the urging means is removed the male member is biased towards and engages with the second magazine.
- 25 14. A delivery device according to claim 13 characterised in that the actuator means comprises at least two radially acting push rod mechanisms which may operate together, independently or sequentially.

15. A delivery device according to Claim 5 characterised in that the medicament metering member comprises a spool and a spool carrier wherein the void between the spool carrier is filled with medicament.
- 5 16. A delivery device according to Claim 15 characterised in that the device is provided with a pair of magazines and said pair of magazines contain the same medicament.
- 10 17. A delivery device according to Claim 15 characterised in that the device is provided with a pair of magazines and said pair of magazines contain different medicaments.
- 15 18. A delivery device according to claim 5 characterised in that the medicament delivery device is an inhaler
19. A delivery device according to claim 2 characterised in that the inhaler is a dry powder inhaler.
- 20 20. A dry powder inhaler comprising a metering member adapted to dispense a measured amount of medicament, an inhalation passage and a mouthpiece, and at least one push rod adapted to move the metering member from a medicament retaining position to a medicament dispensing position characterised in that the push rod moves in a essentially substantially radial direction and actuates the metering member in a substantially radial direction.
- 25 21. A dry powder inhaler comprising a plurality of metering members adapted to dispense a measured amount of medicament and held in a rotatable magazine, an inhalation passage and a mouthpiece, and at least one push rod adapted to move one of the plurality of metering members from a medicament retaining position to
- 30 a medicament dispensing position.

22. A dry powder inhaler according to Claim 17 characterised in that the medicaments are fluticasone and salmeterol.
- 5 23. A dry powder inhaler according to Claim 21 characterised in that the inhaler is provided with two push rods.
24. A magazine comprising a plurality of radially mounted and radially facing spools said spools containing a medicament in dry powder form.
- 10 25. A magazines according to claim 24 characterised in that the magazine is coupled to a second magazine and is provided with an intermediate drive disc.
26. A method of delivering a material which comprises using a delivery device according to Claim 1.
- 15 27. A method of administering a dry powder medicament using a delivery device according to Claim 6.
28. A method according to claim 27 characterised in that a combination of
20 medicaments are administered.
29. A method of treatment of a patient with a respiratory disorder comprising the administration of a therapeutically effective amount of a medicament using an inhaler according to claim 18.
- 25 30. The use of salmeterol and/or fluticasone in the manufacture of an inhaler according to claims 1 or 2.
31. The use of salmeterol and/or fluticasone in the manufacture of a magazine
30 according to claims 24 or 25.

WO 01/17595

PCT/GB00/03377

32. A delivery device substantially as described with reference to the accompanying drawings.

5

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
15 March 2001 (15.03.2001)

PCT

(10) International Publication Number
WO 01/17595 A1

(51) International Patent Classification⁷: **A61M 15/00**

(74) Agent: **HARRISON GODDARD FOOTE**; Tower House, Merrion Way, Leeds LS2 8PA (GB).

(21) International Application Number: **PCT/GB00/03377**

(22) International Filing Date:
4 September 2000 (04.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9920839.9 4 September 1999 (04.09.1999) GB

(71) Applicant (for all designated States except US): **INNOVATA BIOMED LIMITED** [GB/GB]; The Ziggurat, Grosvenor Road, St. Albans AL1 3HW (GB).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **BRAITHWAITE, Philip** [GB/GB]; ML Laboratories Plc, 13 Alexandra Way, Ashchurch Industrial Estate, Tewkesbury GL20 8NB (GB).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

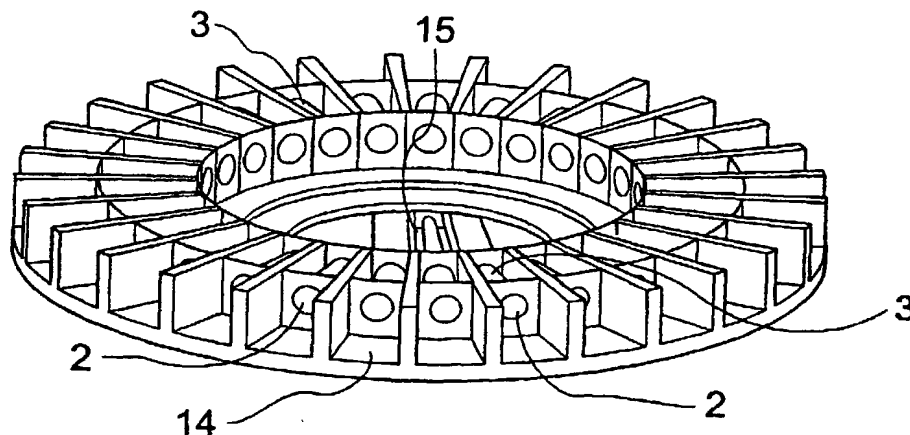
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— With international search report.

[Continued on next page]

(54) Title: **DELIVERY DEVICE**



(57) Abstract: A delivery device, e.g. an inhaler, comprises a rotatable metering member adapted to dispense a measured amount of material, a material delivery passage and a material delivery orifice and at least one actuator member adapted to move the metering member from a material retaining position to a material dispensing position. In a magazine comprising a plurality of metering members, the actuator and metering members may operate in a radial direction. A plurality of rotatable magazines may be utilised in the delivery device. The delivery device may be used to deliver a single or a combination therapy.



WO 01/17595 A1

WO 01/17595 A1



— Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

1/10

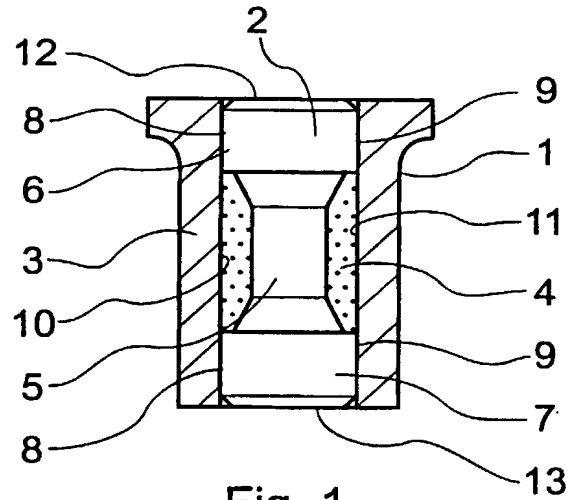


Fig. 1

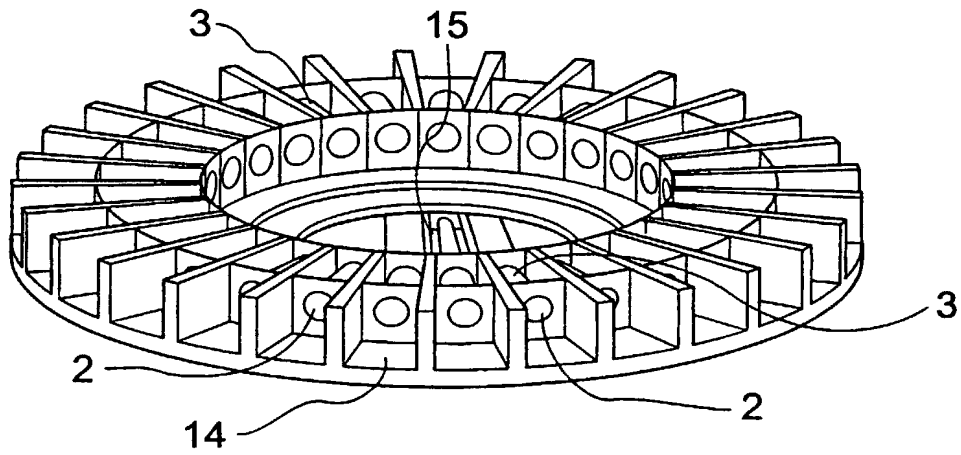


Fig. 2

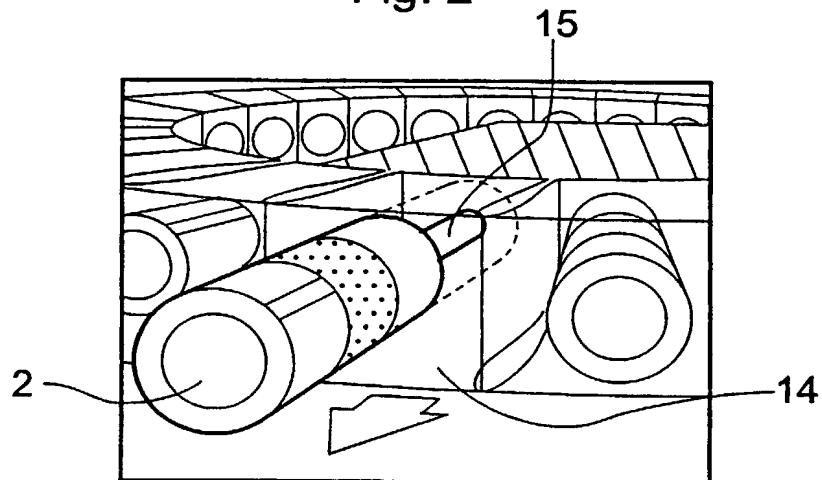


Fig. 3

2/10

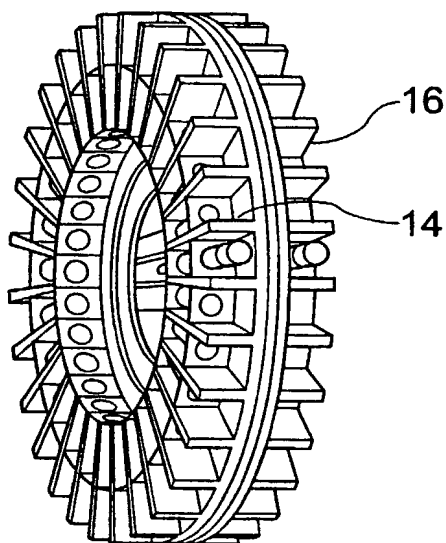


Fig. 4a

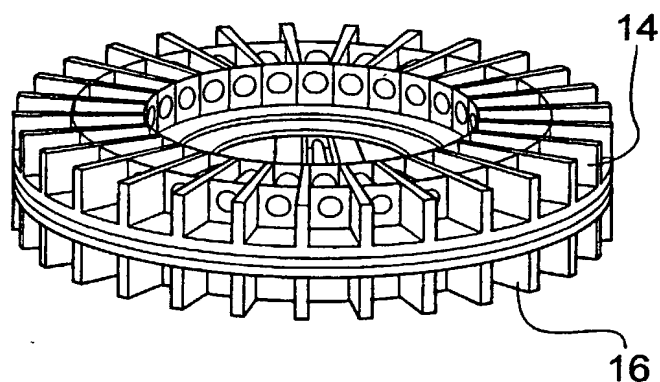


Fig. 4b

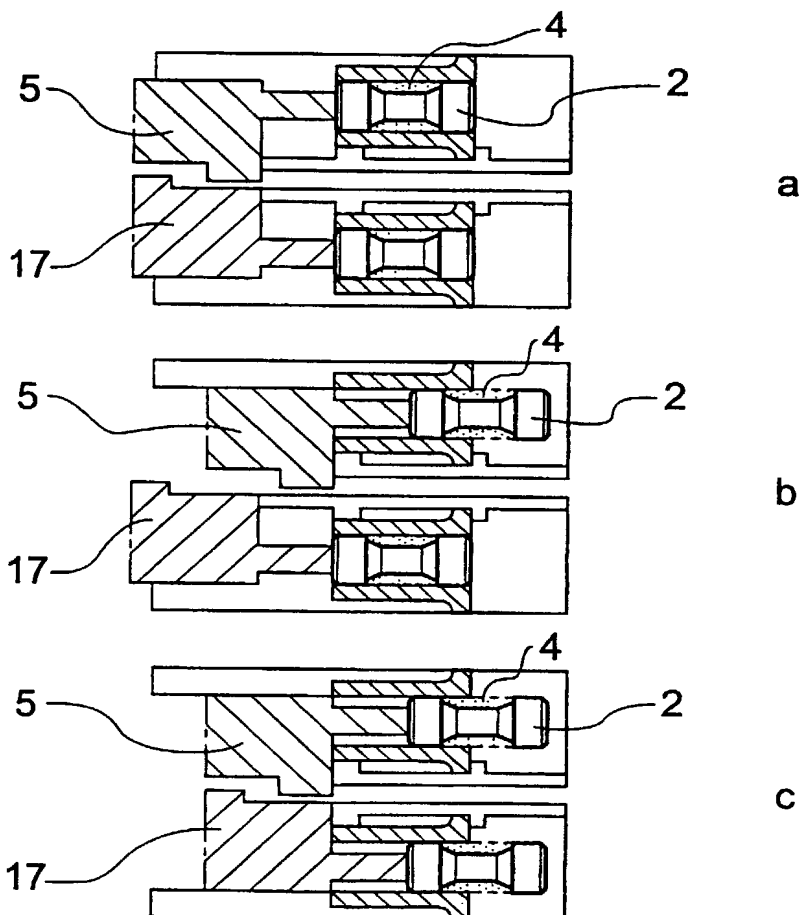


Fig. 5

3/10

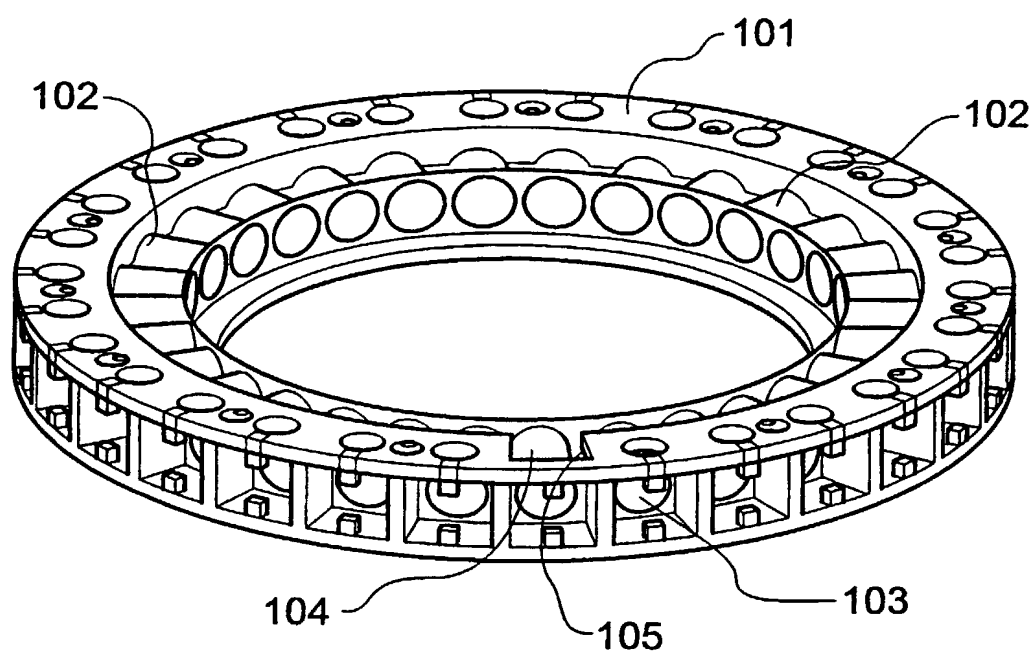


Fig. 6

4/10

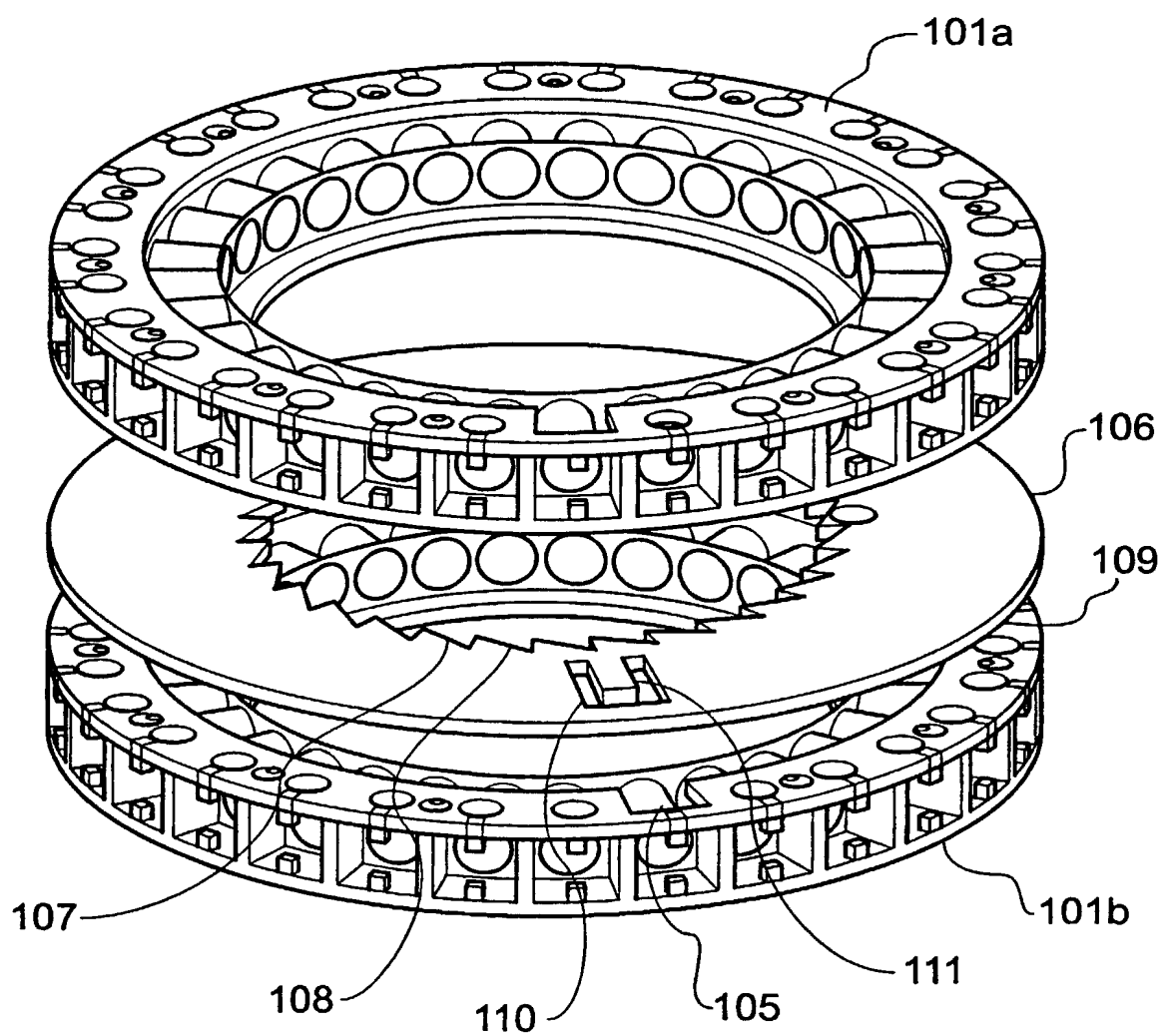


Fig. 7

5/10

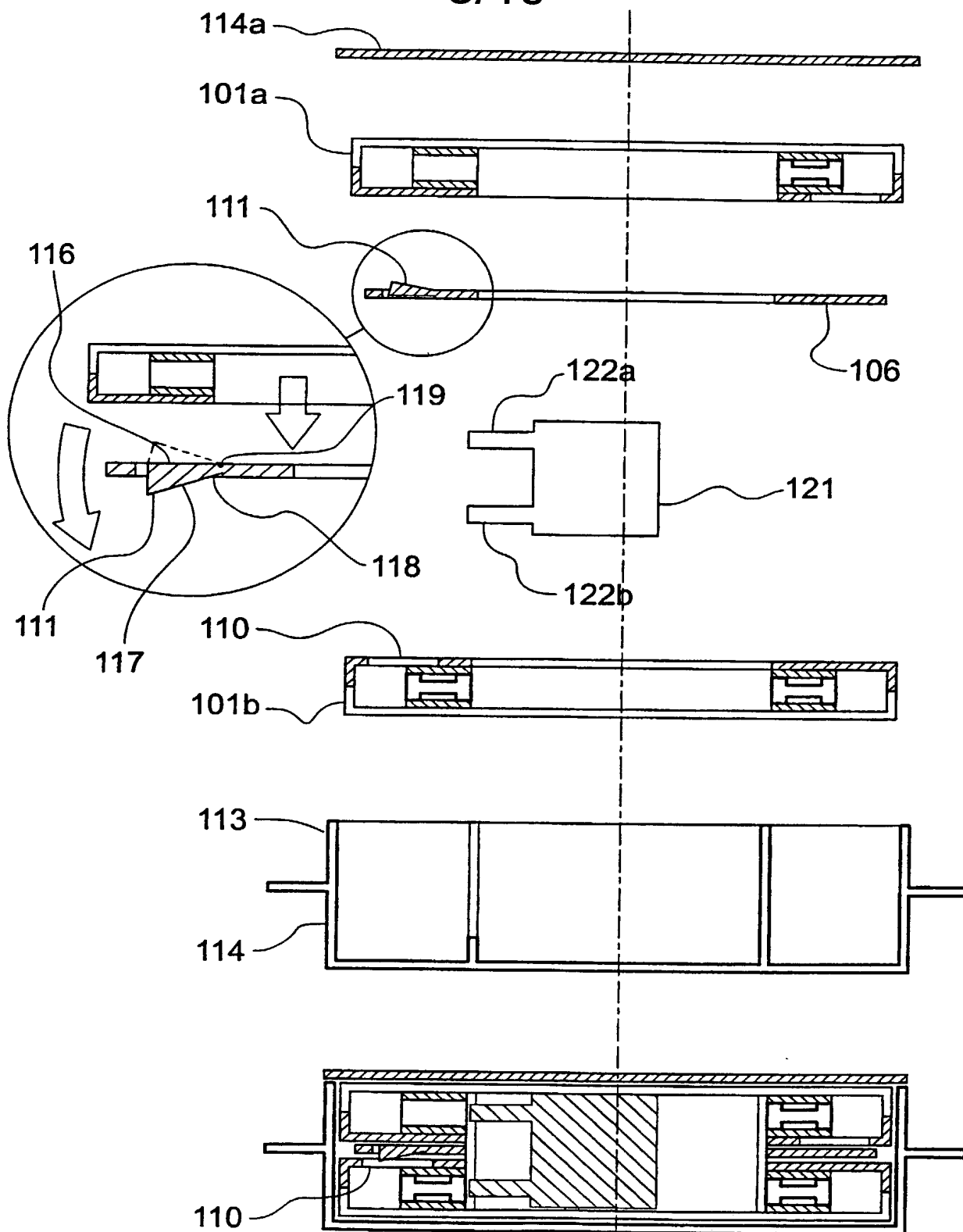


Fig. 8

6/10

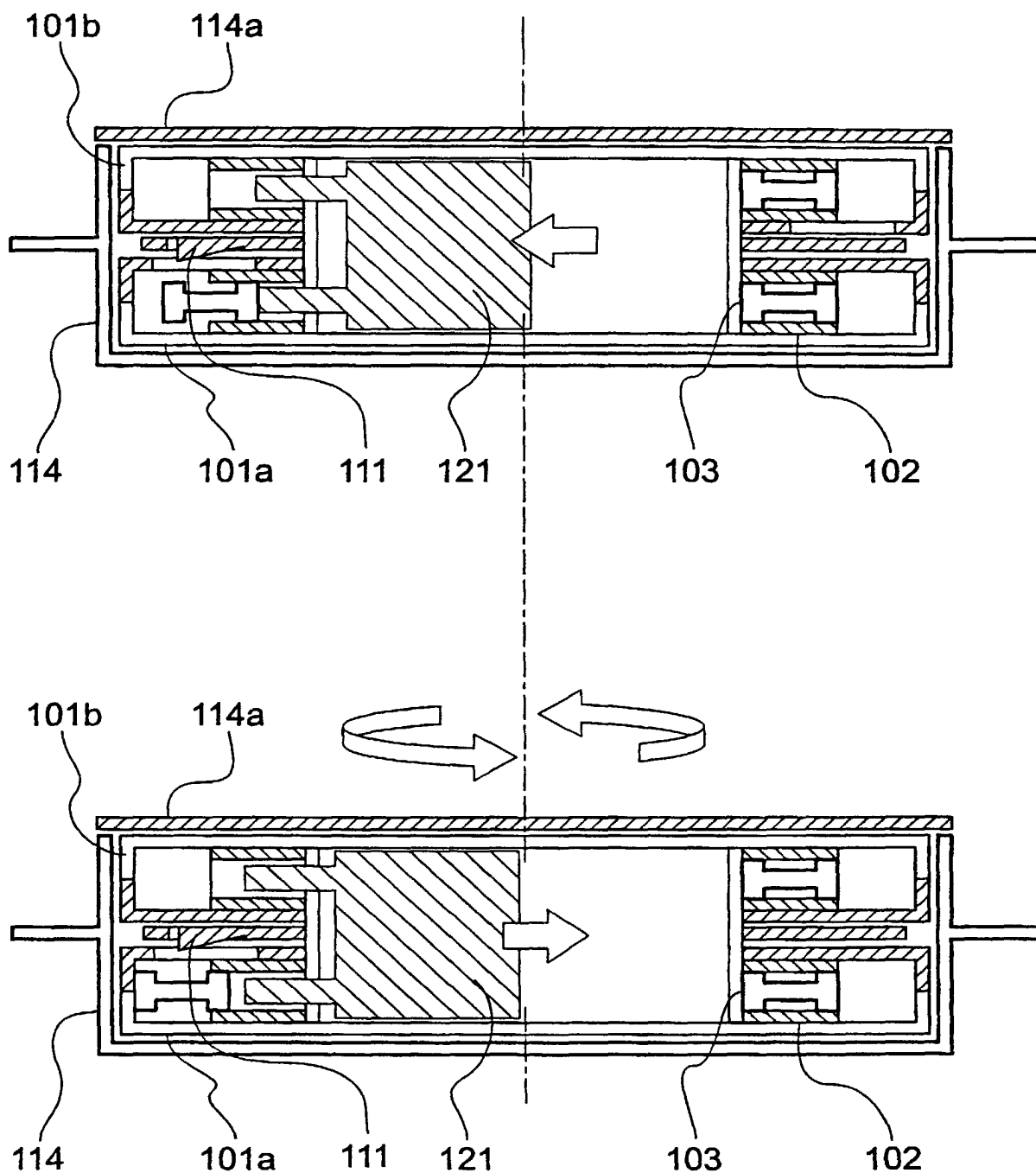


Fig.9

7/10

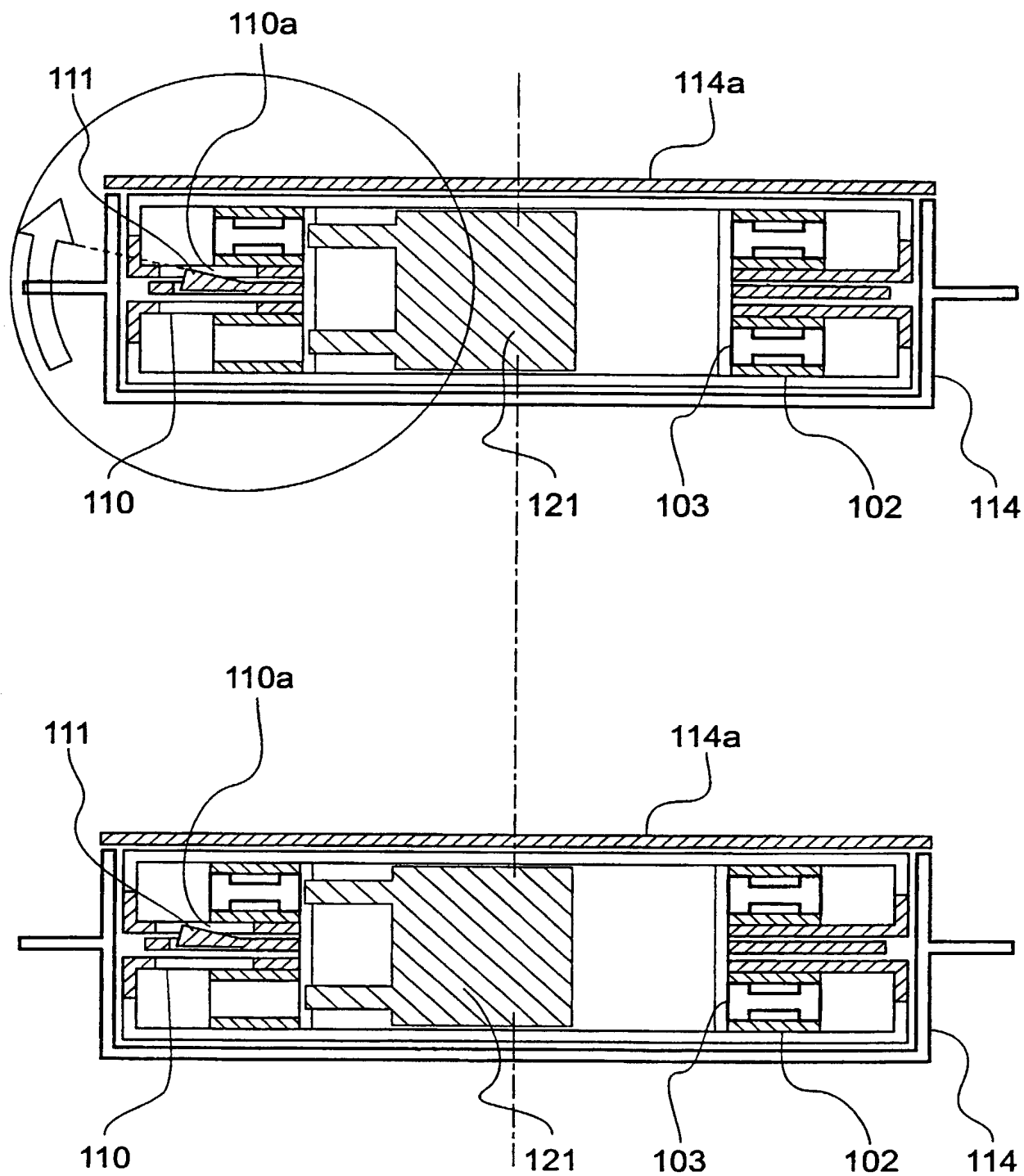


Fig.10

8/10

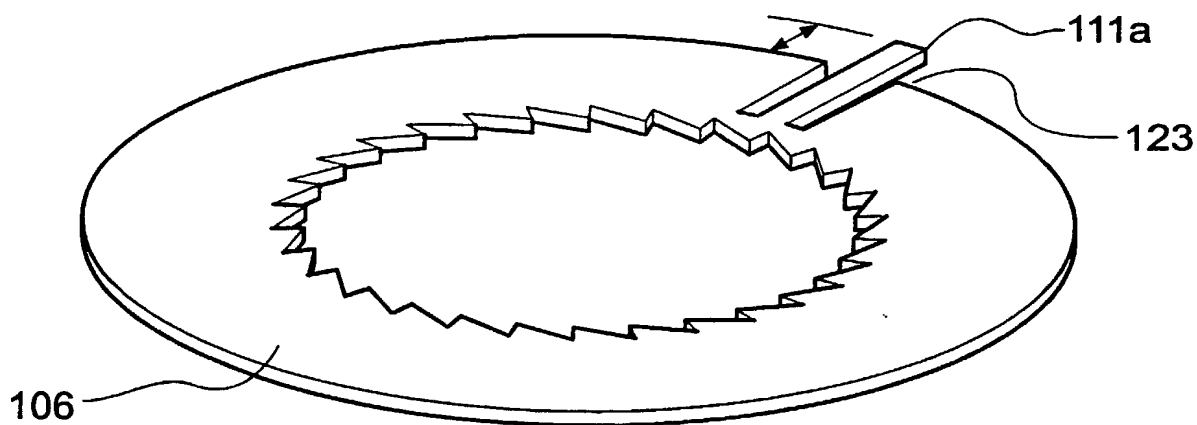


Fig. 11

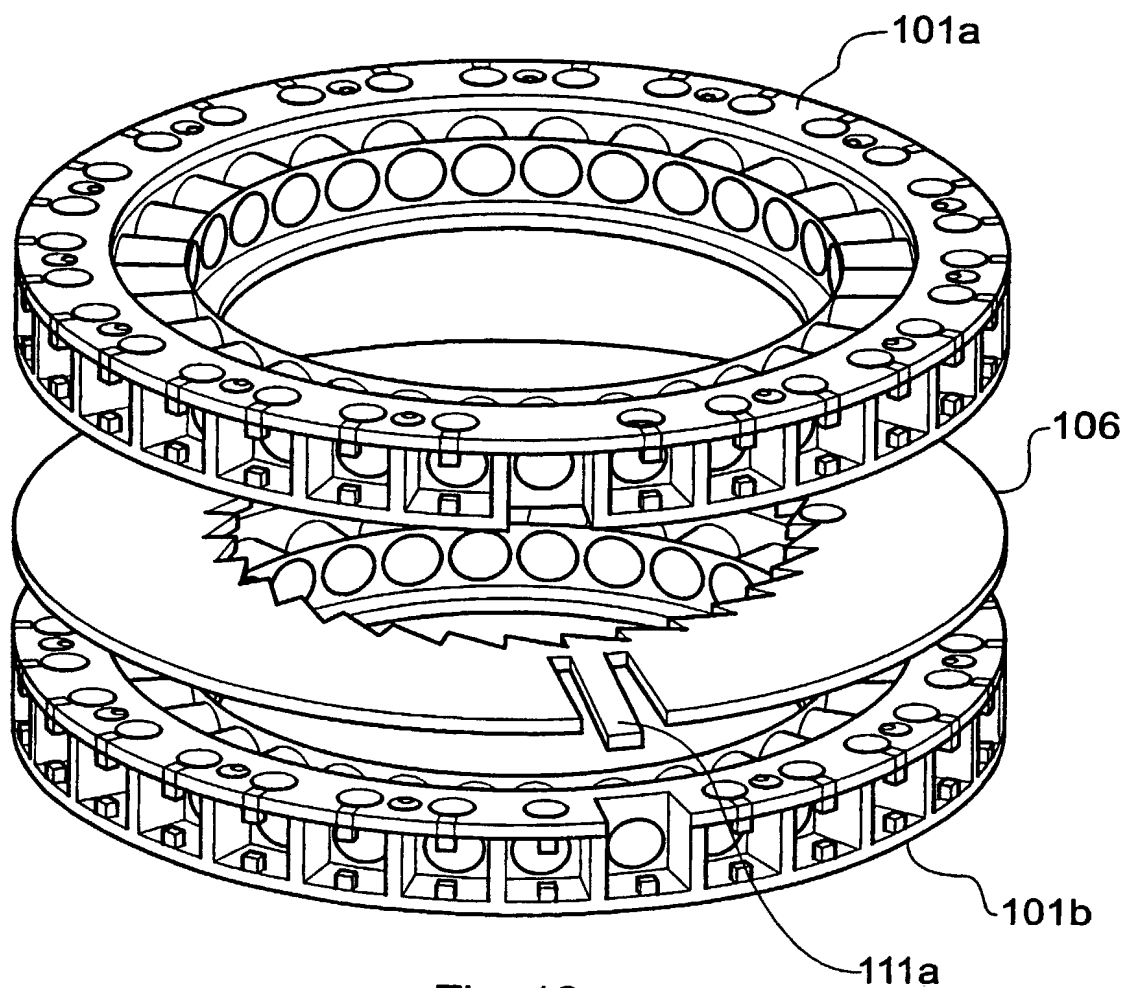


Fig. 12

9/10

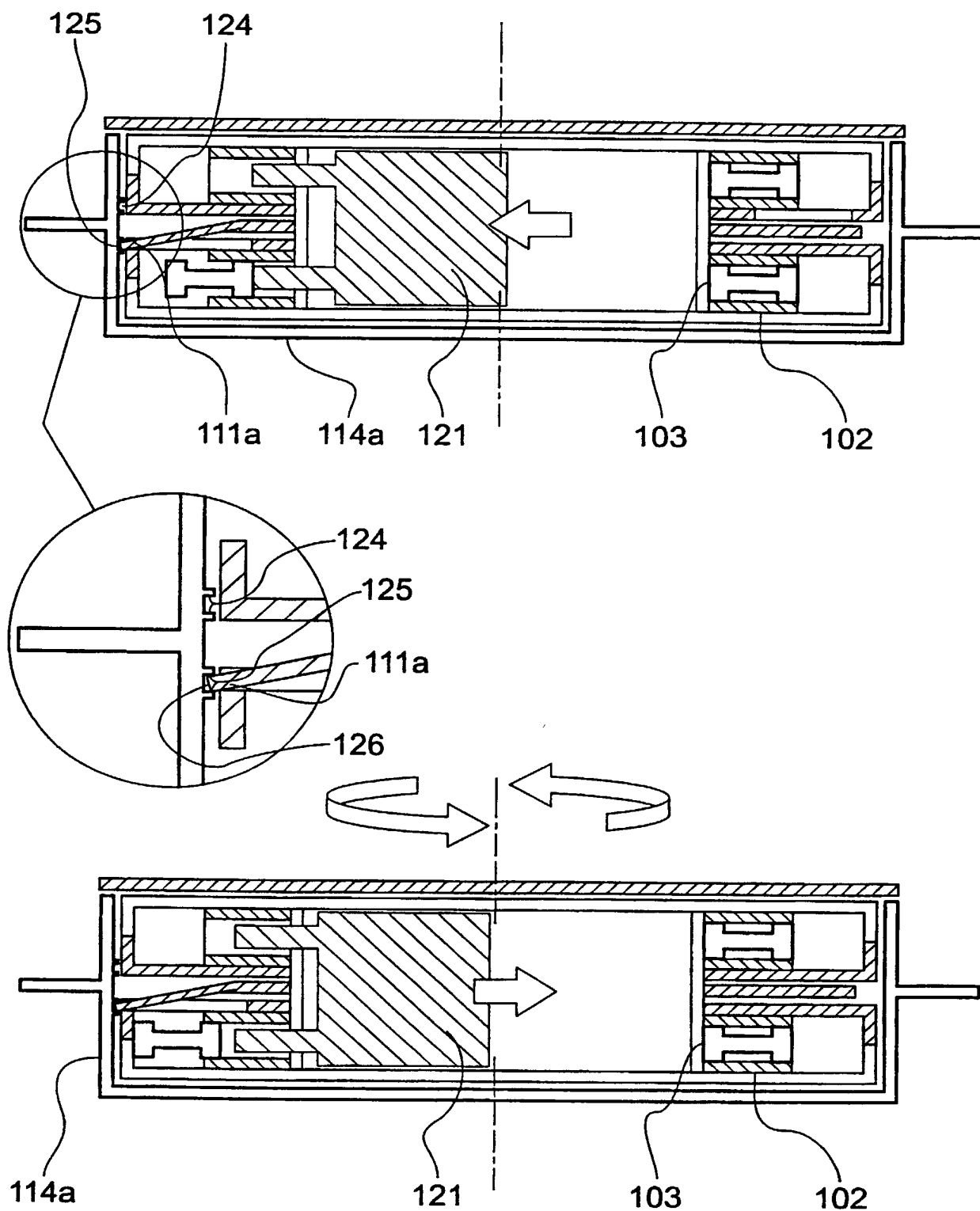


Fig.13

10/10

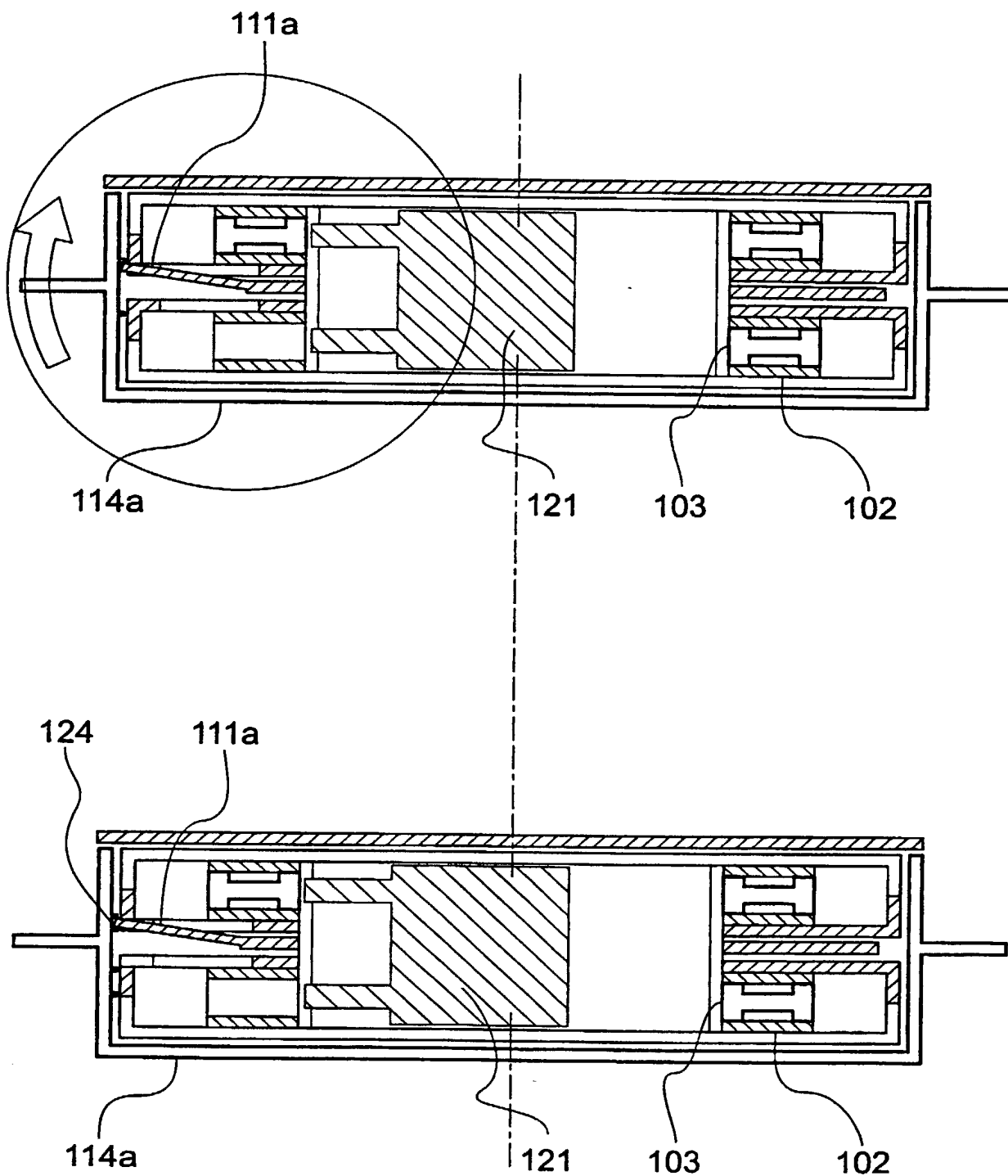


Fig.14

COMBINED DECLARATION AND POWER OF ATTORNEY
(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,
CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is for a national stage of PCT application.

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

DELIVERY DEVICE

SPECIFICATION IDENTIFICATION

The specification was described and claimed in PCT International Application No. PCT/GB00/03377 filed on September 4, 2000.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56, and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent.

**ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

GB 9920839.9, Filed on 4 September 1999

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

APPOINTED PRACTITIONER(S)	REGISTRATION NUMBER(S)
Bruce D. Sunstein	27,234
Robert M. Asher	30,445
Timothy M. Murphy	33,198
Steven G. Saunders	36,265
Karen A. Buchanan	37,790
Samuel J. Petuchowski	37,910
Jeffrey T. Klayman	39,250
John J. Stickevers	39,387
Elizabeth P. Morano	42,904
Jean M. Tibbetts	43,193
Jay Sandvos	43,900
Keith J. Wood	45,235
Alton Hornsby, III	47,299
Alexander J. Smolenski	47,953
John L. Conway	48,241

I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

[illegible]

Robert M. Asher
125 Summer Street
Boston, MA 02110-1618
US

~~Customer Number 002101~~

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

100

Inventor's signature

Residence Tewkesbury GB

Post Office Address

ML Laboratories Plc, 13 Alexandra Way, Ashchurch Industrial Estate, Tewkesbury GL20 8NB GB

Country of Citizenship GB

CBX

Inventor Information

Inventor One Given Name:: Philip
Family Name:: Braithwaite
Postal Address Line One:: ML Laboratories Plc
Postal Address Line Two:: 13 Alexandra Way
Postal Address Line Three:: Ashchurch Industrial Estate
City:: Tewkesbury
Postal Code:: GL20 8NB
Country:: United Kingdom
Citizenship Country:: United Kingdom

Correspondence Information

Correspondence Customer Number:: 2101
Electronic Mail:: rasher@bromsun.com

Application Information

Title Line One:: Delivery Device
Total Drawing Sheets:: 10
Formal Drawings?:: Yes
Application Type:: Utility
Docket Number:: 2245/108

Representative Information

Representative Customer Number:: 2101

Continuity Information

This application is a:: 371 of
> Application One:: PCT/GB00/03377
Filing Date:: 04 September 2000

Prior Foreign Applications

Foreign Application One:: 9920839.9
Filing Date:: 04 September 1999
Country:: GB
Priority Claimed:: Yes